

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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(4)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/444,934	05/22/95	LAWN	R MSM101CONTC

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EXAMINER
JACOBSON, D

ART UNIT	PAPER NUMBER
1652	33

DATE MAILED: 01/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 08/444,934	Applicant(s) Lawn
Examiner Jacobson	Group Art Unit 1652

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on NOV. 30, 1998.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

Claim(s) 4-6, 8, 20-21, 23-25, 27-29, 31-41 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) 24, 25 is/are allowed.

Claim(s) 4-6, 8, 20-21, 23, 27-29, 31-36, 38-41 is/are rejected.

Claim(s) 37 is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - All Some* None of the CERTIFIED copies of the priority documents have been received.
 - received in Application No. (Series Code/Serial Number) _____.
 - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of References Cited, PTO-892
- Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Other _____

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Claims 4-6, 8, 20-21, 23-25, 27-29, and 31-41 are pending in the present application.

The previous 35 U.S.C. 102(b) rejection over Broze et al. has been withdrawn in light of applicants' arguments and explanations.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6, 8, 20-21, 23, 27-29, 31-36, and 38-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record, with the exception of claims 24-25. Applicants' arguments are persuasive concerning the rejection of claims 24-25 and the rejection of those claims is withdrawn.

The specification discloses the complete amino acid and cDNA sequence of human tissue factor protein. The specification suggests deleting the transmembrane domain, residues 220-242, for example (page 13) or deletion the glycosylation sites (page 16). No other deletion variants are suggested by applicants. The examples do not describe construction of any deletion variants, only cloning and determining the sequence encoding human tissue factor protein.

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In their response of 11/30/98 applicants traverse this rejection. Applicants argue that deletion variants are adequately described by the specification. Applicants cite case law and argue that the subject matter of a claim need not be described literally; it only needs to be conveyed to those skilled in the art. Applicants further assert that the examiner has misconstrued the Konigsberg declaration. Applicants refer to figure 5 and page 15 of the specification. These arguments have been fully considered but are not deemed to be persuasive.

The specification contains the following references to deletion variants:

-- page 7, lines 11-16. ".....novel tissue factor protein derivatives.....lacking the signal sequence and the hydrophobic portion of the protein....."

--page 12, line 31 to page 13, line 35. "Deletions are characterized by the removal of one or more amino acid residues.....no more than about from 2 to 6 residues are deleted....Another deletion is of the transmembrane domain located at about residues 220 to 243...deletions will range about from 1 to 30 residues."

--page 15, line 20 to page 16, line 5. "A major class of.....deletional variants are those involving the transmembrane, i.e., hydrophobic or lipophilic, region.....The transmembrane region of tissue factor protein is located at about residues 220 to 242...."

The specification clearly describes deletion of the transmembrane domain, which is defined as residues 220 to 243. The specification does not specifically describe deletion of other residues.

Applicants are correct that all embodiments need not be specifically described in the specification. However, the specification needs to demonstrate that applicants were in possession

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of the claimed invention. “[T]he ‘essential goal’ of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed.” *In re Barker*, see MPEP 2163. “An applicant’s specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, i.e., whatever is now claimed.” *Vas-Cath, Inc. v. Mahurkar*, see MPEP 2163. “An objective standard for determining compliance with the written description requirement is ‘does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.’” MPEP 2163.02. The written description requirement must be determined on a case-by-case basis and is a question of fact. MPEP 2163.04.

As discussed above, the specification contains specific references to deletion of residues 220 to 243, which is the transmembrane domain. This deletion variant is supported by the specification in such a manner as to convey to one of skill in the art that applicants were in possession of this deletion variant. The specification does not contain specific reference to other deletion variants. Should one of skill in the art read the present specification one would not recognize that applicants had possession of other deletion variants. Other deletion variants are not conveyed to the skilled artisan. The evidence is that (1) a deletion variant lacking residues 220 to 243 is described, and (2) other deletion variants, such as those claimed are not described by the specification.

In their response applicants assert that the examiner has “misconstrued” the Konigsberg Declaration. The declaration has been reconsidered by the examiner. Dr. Konigsberg is correct

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that the cytoplasmic domain of the tissue factor protein does not affect functionality of the protein. However, the specification by itself does not lead one of skill in the art to delete the cytoplasmic domain residues. As discussed above, the specification clearly suggests, at several locations, to delete the transmembrane domain, residues 220 to 243. The specification is silent as to deletion of the cytoplasmic domain. The specification does not convey to one skilled in the art that applicants were in possession of or had contemplated a tissue factor variant that also lacked the cytoplasmic domain. Therefore, while the declaration is relevant, it fails to demonstrate that the specification suggests or teaches deletion of the cytoplasmic domain.

Figure 5 depicts the hydropathy profile of tissue factor. It shows the predicted hydrophobic membrane spanning domain encompassed by residues 220 to 243. See page 9, lines 13-25. Figure 5 does not suggest or convey construction of deletion variants. It only shows where the hydrophobic domain is located within the molecule.

Page 15, lines 20-26, states, "A major class of....deletional variants are those involving the transmembrane, i.e., hydrophobic or lipophilic, region....The transmembrane region of tissue factor protein is located at about residues 220 to 242...." This passage does not convey to one of skill in the art that applicants were in possession of other deletion variants at the time the invention was made.

On pages 9-16 of their response applicants argue that the claimed proteins are enabled by the specification and that the claimed invention is not beyond the scope of the enabling disclosure. These arguments have been considered but are not pertinent to the present rejection. The

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rejection is one of lack of written description, **not** one of lack of enablement. MPEP 2161 clearly states that the three requirements of 35 U.S.C. 112, first paragraph (written description, enablement, and best mode) are separate and distinct from each other. Applicants' arguments regarding enablement are noted, but are not specifically addressed because they are not relevant to the above written description rejection.

Claims 4-6, 8, 20-21, 23, 27-29, 31-36, and 38-41 stand rejected under 35 U.S.C. 112, first paragraph, for the above reasons.

Claims 24-25 are ALLOWABLE. Claim 37 is objected to as depending from a rejected claim.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dian C. Jacobson whose telephone number is (703) 308-2973. The examiner can normally be reached Monday, Tuesday, and Thursday from 7:30 to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at (703) 308-4216. The official FAX number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Dian Jacobson
DIAN C. JACOBSON
PRIMARY EXAMINER
GROUP 1652 1600